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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/536,111 03/24/00 DARASCH

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HM22/0809

EXAMINER

ZEMAN, M	
ART UNIT	PAPER NUMBER

1631
DATE MAILED:

7
08/09/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/536,111

Applicant(s)

DARASCH ET AL.

Examiner

Mary Zeman

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 March 2000 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Art Unit: 1631

DETAILED ACTION

Claims 1-22 are pending in this application.

Applicant's election with traverse of Group I in Paper No. 6 is acknowledged. The traversal is on the ground(s) that the searches are substantially co-extensive both in US Patents, and literature, and that the search of the computer system implementing the methods would not be an additional search burden. Applicant's arguments are persuasive, and all claims presently pending will be examined herein.

Information Disclosure Statement

The Information Disclosure Statement, filed 8/17/00, has been entered and considered. An initialed copy of the form PTO-1449 is enclosed with this action.

Drawings

Applicant is required to submit a proposed drawing correction in reply to this Office action. Due to changes in Office procedure, formal correction of the noted defect **can no longer be deferred** until the application is allowed by the examiner.

In particular, the drawings having graphs are difficult to read. Not all the information in the graphs and the legends are readable. In the figure depicting a computer system, not all the lines are legible.

Further, the drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference sign(s) not mentioned in the description: In Figure 6, parts "10"- "16" are depicted. The disclosure does not appear to contain a definition or description of the part identified as "12". Correction is required.

Applicant is reminded that changes to the drawings may require parallel changes to the specification to the Brief Description of the Drawings.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Art Unit: 1631

Claims 8, 9, 10, 14, 15, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 8 recites the limitation "the order of the polynomial" in reference to claim 6, which depends from claim 1. Neither claim 1, nor claim 6 recite "an order of a polynomial" nor do they recite "a polynomial". There is insufficient antecedent basis for this limitation in the claim.

Claim 9 is unclear as it calls for a plurality of experimental DNA sequencing traces, while claim 1, from which claim 9 depends, only recites use of a *single* experimental DNA sequencing trace. Claim 10 similarly requires multiple experimental traces.

In claim 14, it is unclear which experimental trace is being run with the first reference in the common lane, as claim 11, from which claim 14 ultimately depends, recites multiple experimental data traces.

In claim 15, it is unclear where the multiple separations of the reference fragments takes place- do they take place in a common lane? A common gel? Across multiple gels?

Claim 16 recites the limitation " the polynomial" in reference to claim 11. Claim 11 does not recite "a polynomial". There is insufficient antecedent basis for this limitation in the claim.

Claim 19 recites the limitation " the polynomial" in reference to claims 18, 17 and 11. None of claims 11, 17 and 18 recite "a polynomial". There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 1, 2, 5-13, and 16-22 are rejected under 35 U.S.C. 102(b) as being anticipated by Koutny et al. (1992).

Claim 1 is drawn to a method of assigning base numbers to peaks in a DNA sequence data trace. This is done using a reference trace, which has been corrected in its time scale to make the spacing of the peaks fairly regular. The experimental trace is then compared to the reference trace at the same place that peaks appeared in the reference. Any peak corresponding to the reference is assigned a base number. Claim 11 allows for multiple experimental traces and one or more reference traces to be used. The traces can be obtained from experiments run in a common gel, and a defined number of bands can be analyzed. Claims 2 and 12 set forth that the comparison and evaluation of the reference trace include identifying a set of coefficients for a polynomial effective to linearize a plot of peak number versus separation between peaks. These coefficients are used to produce a corrected time scale. The polynomial used can be third order or higher. Claims 21 and 22 are drawn to apparatus for performing the methods.

Koutny et al. (Applied Spectroscopy (1992) Vol. 46 No. 1 pages 136-141; PTO-1449) disclose automated methods for analyzing sequence data traces wherein a certain number of peak locations are analyzed and identified, and entered into a data array (table). Next, third-order polynomial regression is used to evaluate the reference sequence and the peak locations in order to "straighten" or make regular the peaks in the data trace (correcting the time scale) and base numbers are then assigned (See figures 3 and 6). Next, traces from differing lanes of the gel are normalized to one another (Fig 7). Koutny et al. note that the algorithms for these methods were coded in Turbo Basic on a computer system which has input and output means, processing means, etc (p140).

Claims 1, 3, 6, 7, 11, 13, 14, 17, 18 and 21 are rejected under 35 U.S.C. 102(e) as being anticipated by Gabe et al. (US 5,981,186).

Gabe et al. (US 5,981,186 ; PTO-1449) disclose methods of assigning base numbers to peaks of DNA sequencing data traces. The sequencing reactions can be run in a single lane if the labels for each reaction are distinguishable, or they can be run in differing lanes on a common gel. Figure 1 is an example of base numbers assigned to two traces. The different traces can be aligned and normalized to have a standard spacing between the peaks- a methods of correcting a

Art Unit: 1631

time scale. Gabe et al. also disclose an apparatus for performing the methods, which comprise a processor, input, output, and particular algorithms.

Claims 1, 2, 4, 6-13, 15, and 17-22 are rejected under 35 U.S.C. 102(b) as being anticipated by Green et al. (US 5,853,979).

Green et al. disclose methods for analysis of DNA sequence traces wherein experimental data is compared to a reference trace. In the analysis, the spacing between peaks of a reference trace is normalized using a second order polynomial function to give a corrected time scale. The normalized trace is used to identify and number peaks in the experimental trace for later decoding into sequence data. Green et al. also disclose automated systems programmed to carry out these methods.

Claims 1, 2, 4-13, and 15-22 are rejected under 35 U.S.C. 102(e) as being anticipated by Gilchrist et al. (US 5,916,747).

Gilchrist et al. disclose methods for analysis of DNA sequence traces wherein one or more experimental data traces are compared to a reference trace. In the analysis, the spacing between peaks of a reference trace is normalized using a second order polynomial or higher function to give a warp factor, or corrected time scale. The normalized trace is used to identify and number peaks in the experimental trace for later decoding into sequence data. Gilchrist et al. also disclose automated systems programmed to carry out these methods.

Claims 1, 11 and 21 are rejected under 35 U.S.C. 102(e) as being anticipated by Imai (US 5,891,632).

Imai discloses methods of assigning base numbers and positions to sequencing data traces compared against a reference sequence. The reference trace is normalized and corrected for even spacing between the peaks, resulting in a corrected time scale. Then the experimental traces are aligned and base position and type are determined. Imai also discloses an apparatus programmed for carrying out the methods.

Art Unit: 1631

Conclusion

No claim is allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Marks et al. (US 6,208,941 B1) discloses base calling algorithms based upon fuzzy logic.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary K Zeman whose telephone number is (703) 305-7133. The examiner can generally be reached between the hours of 7:30 am and 5:00 pm Monday through Thursday, and on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached at (703) 308-4028.

The official fax number for this Art Unit is (703) 308-4242. An unofficial fax number, direct to the Examiner is 703 746 5279. Please call prior to use of this number.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Patent Analyst Tina Plunkett whose telephone number is (703) 305-3524.

mkz
8/1/01


MARY K. ZEMAN
PATENT EXAMINER
